

Final report → When + where does info put in note at lab level appear.

Current Data Review & Approval Guidelines for Analytical Testing

Test (number of reps)	Technician			Technical Leadership (TL)		
	Responsibilities for reviewing test results	Criteria for reviewing, rejecting, & rechecking	Requirements for recording data rejection	Responsibilities for reviewing test results	Criteria for approving, rejecting, & rechecking	Requirements for recording data rejection
<ul style="list-style-type: none"> • FTC-Nic (8,16) • FTC-H₂O (8,16) • Rotary Nic (2,4) • Rotary H₂O (2,4) • Filtrona Nic (8,16) • Filtrona H₂O (8,16) 	<ul style="list-style-type: none"> • PPI 095-405 • Print preliminary report • Check instrument ran properly/consistent • Check RT Diff ≤ 1.00 min • Check ISTD <i>for consistency</i> • Check R² range (0.9980 - 1.000) • Check Stdev blanks ≤ 0.015 • Check Conc. 5 <i>in inc order</i> • Ckstd# 3 plotted CC and within UCL & LCL • Samples properly barcoded • Data values for all samples • Negative H₂O values (if below lowest Std edited to 0.001) • Commit Data <p><i>All in PPI & straight forward</i></p>	<ul style="list-style-type: none"> • If questionable criteria from previous column warrants rerun sample(s); reprocess data • If still out - notify TL • Reject if assignable cause: broken test tube, equipment malfunctioned, operator technique • N.D. set to missing • If missing samples (test tubes from smoke lab) set Nic & H₂O to missing 	<ul style="list-style-type: none"> • Enter in computer notes editing • Notify TL if retesting is necessary 	<ul style="list-style-type: none"> • Review only results not automatically approved by computer (Status 50 report) • Check outlier has run • Assure there is data for all test • Assure correct number of values • Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. <p><i>Accepted for limits for different countries</i></p>	<ul style="list-style-type: none"> • Investigate if higher than acceptable criteria or data is missing • Investigate if H₂O SD > 0.5 • Approve data if check of all smoke parameters follows the trends of TPM and Puff count • Approve data if check of Instrument and control charts are okay • Approve Rotary Nic/Tar (2 values difference between two values ≤ 15% or 1.0 mg/cig (tar); 0.1 mg/cig (nic) which ever is greater) • If rotary smoke has 4 values, use same SD criteria • If recheck necessary, notify Smoke Lab TL to set up resmoke <p><i>Will be replaced by range criteria. Based on average of data, what is an acceptable SD?</i></p>	<ul style="list-style-type: none"> • Enter in computer notes editing • Record in log book if analytical reason for recheck

Checklist for determining that GC is running correctly

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check SD
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good data

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Men-Smoke (8)	<ul style="list-style-type: none"> PPI 095-407 Print preliminary report Check instrument ran properly/consistent Check RT Diff \leq 1.00 min Check ISTD Check R² range (0.9980 - 1.000) Check Conc. Men-TA Monitor plotted on CC and within UCL & LCL Samples properly barcoded <i>seen</i> Proper Multiplier <i>right</i> Data values for all samples Commit Data 	<ul style="list-style-type: none"> If questionable criteria from previous column warrants rerun sample(s); reprocess data If still out - notify TL Reject if assignable cause: broken test tube, equipment malfunctioned, operator technique N.D. set to missing Missing samples (test tubes from smoke lab) set Men to missing <p><i>Set Men TPM to PC to reject</i></p>	<ul style="list-style-type: none"> Enter in computer notes editing Notify TL if retest is necessary 	<ul style="list-style-type: none"> Review only results not automatically approved by computer (Status 50 report) Check outlier has run Assure there is data for all test Assure correct number of values Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. 	<ul style="list-style-type: none"> Investigate if higher than acceptable criteria Approve data if check of all smoke parameters follows the trends of TPM and Puff count Approve data if check of Instrument, control charts, and multipliers are okay <p>If recheck necessary, notify Smoke Lab TL to set up resmoke</p>	<ul style="list-style-type: none"> Enter in computer notes editing Record in log book, if analytical reason for recheck <p><i>Is that necessary since putting in notes editing.</i></p>
Menthol in Filler (2) Menthol in Plug (2) Menthol on Foil (3)** Total menthol (1) Flt-TA (1) Flt-TAI (1)	<ul style="list-style-type: none"> PPI 095-410 and PPI 095-420 Print preliminary report Check instrument ran properly/consistent Check RT Diff \leq 1.00 min 	<ul style="list-style-type: none"> If questionable criteria from previous column warrants rerun sample(s); reprocess data If still out - notify TL Reject if assignable 	<ul style="list-style-type: none"> Enter in computer notes editing Notify TL if retesting is necessary 	<ul style="list-style-type: none"> Review only results not automatically approved by computer (Status 50 report) Check outlier has run Assure correct 	<ul style="list-style-type: none"> No set criteria Approve, if process is in control, and samples with more than one value, the values are close to the same proximity **Has SD criteria to follow 	<ul style="list-style-type: none"> Enter in computer notes editing

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Flt-TAO (1)	<ul style="list-style-type: none"> Check ISTD Check R^2 range (0.9980 - 1.000) Check Conc. Men-TA Monitor plotted on CC and within UCL & LCL Samples properly barcoded Proper Multiplier Data values for all samples Commit Data 	<ul style="list-style-type: none"> cause: broken test tube, equipment malfunctioned, operator technique N.D. set to missing 		<ul style="list-style-type: none"> number of values Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. 		
CO (2)	<ul style="list-style-type: none"> Ensure Equipment runs properly/consistent Monitor run plotted on CC & within limits Ensure proper number of values 	<ul style="list-style-type: none"> PPI 095-205 Samples with 4.0 mg/cig or less tar level - difference \geq 0.7 mg/cig, recheck Samples greater than 4.0 mg/cig tar level - difference \geq 1.0 mg/cig, recheck Reject if assignable cause: defective cigt, operator technique, equipment malfunction <p><i>Too many rechecks</i></p>	<ul style="list-style-type: none"> Log recheck in log book Enter in computer notes editing 	<ul style="list-style-type: none"> Review samples from Status 50 report <p><i>All OK's come up to be reviewed & approved.</i></p>	<ul style="list-style-type: none"> Approve samples with 4.0 mg/cig or less tar level - difference \leq 0.7 mg/cig, else recheck Approve samples greater than 4.0 mg/cig tar level - difference \leq 1.0 mg/cig, else recheck <p>Guidelines</p> <ul style="list-style-type: none"> Average \pm 1.0 mg/cigt from tar spec (if available) or smoked tar value of sample (preferred) <p><i>need better guidelines</i></p>	<ul style="list-style-type: none"> Enter in computer notes editing Recheck barcode taken to GPI Tech

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					comparison) • Average ± 2.0 mg/cigt from smoked tpm value of sample (in cases when tar values are not available)	
NO (2) HCN (2) RCHO (2) RCHOP (2) HCNOP (2)	<ul style="list-style-type: none"> PPI 095-205 Ensure Equipment runs properly/consistent Monitor run plotted on CC & within limits Ensure proper number of values 	<ul style="list-style-type: none"> No set criteria; values close to same proximity Reject is assignable cause: defective cigt, operator technique, equipment malfunction 	<ul style="list-style-type: none"> Log recheck in log book Enter in computer notes editing 	<ul style="list-style-type: none"> Review samples from Status 50 report 	<ul style="list-style-type: none"> No set criteria; values close to same proximity <p><i>What's pretty close</i></p>	<ul style="list-style-type: none"> Enter in computer notes editing All associated tests must be rechecked - recheck barcode taken to GPI Tech